

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US04/41921

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC(7)	: G01 N 33/53, 33/567; c07 k 16/18, 7/64	
US CL	: 435/7.2; 530/317, 388.25	
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 435/7.2; 530/317, 388.25		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	PGPUB 20030235868 (HOOGENBOOM et al ) 25 December 2003, Abstract and detailed description of the invention, in particular.	1-78
Y	US 5,861,381 (CHAMBON et al) 19 January 1999, Abstract and detailed description of the invention, in particular.	1-78
Y	PGPUB 20040054137 (THOMPSON et al) August 4th, 2003, Abstract and the the brief description the invention, in particular.	1-78
Y	PBPUB 20050042209 (KUFE et al) Priority date September 11th, 2000, Abstract and Brief description of the invention in particular.	1-78
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents:		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search		Date of mailing of the international search report
06 February 2006 (06.02.2006)		22 MAR 2007
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner of Patents P.O. Box 1450 Alexandria, Virginia 22313-1450		Authorized officer Parithosh K. Tungathur
Facsimile No. (571) 273-3201		Telephone No. (571) 272-0600

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
STEPHANA E. PATTON  
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BOSTON, MA 02205

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference <b>59849 PCT (</b>		Date of mailing (day/month/year) <b>22 MAR 2007</b>
International application No. <b>PCT/US04/41921</b>		International filing date (day/month/year) <b>10 December 2004 (10.12.2004)</b>
International Patent Classification (IPC) or both national classification and IPC <b>IPC(7): G01 N 33/53, 33/567; c07 k 16/18, 7/64 and US Cl.: 435/7.2; 530/317, 388.25</b>		Priority date (day/month/year) <b>12 December 2003 (12.12.2003)</b>
Applicant <b>GOVT. OF THE US AS REPRESENTED BY THE SECRETARY, D</b>		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion <b>06 February 2006 (06.02.2006)</b>	Authorized officer <b>Parithosh K. Tongatur</b> Telephone No. (571) 272-0600
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Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/41921

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☒ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☒ on paper
- ☒ in electronic form
- c. time of filing/furnishing
- ☒ contained in the international application as filed.
- ☒ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-78</u>	NO
Inventive step (IS)	Claims <u>1-78</u>	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims <u>1-78</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-78 lack an inventive step under PCT Article 33(3) as being obvious over Chambon et al (U.S. Patent 5,861,381; date issued January 19, 1999) and in view of Hoogenboom et al (PGPUB 20030235868; Priority claimed April 22, 2002)

The instant claims are summarized as isolated nucleic acid molecule which encodes an agonist polypeptide antigen derived from MUC-1, wherein the agonist polypeptide stimulates an immune response, a method for generating an immune response to a MUC-1 tumor antigen comprising administering an isolated nucleic acid molecule. A method of treating a subject and a method of screening a molecule to generate an immune response to a MUC-1 to a tumor antigen.

Chambon et al teach a pharmaceutical composition comprising SEQ ID NO:1,2,3,4,5,6,7,8, 9, 10 of the instant application intended for the curative treatment or the prevention of a malignant tumor, more especially of a carcinoma and most especially of a breast cancer a method of screening a molecule to generate an immune response to a MUC-1 to a tumor antigen. Chambon et al does not teach the method of identifying the molecule to generate an immune response to a MUC-1 to a tumor antigen.

Hoogenboom et al teach agonist polypeptide antigen derived from MUC-1 wherein the agonist polypeptide stimulates an immune response and a method of identifying a molecule that has the ability to generate an immune response to MUC-1.

It would have been obvious to combine the teachings of Chambon et al and Hoogenboom et al a method for generating an immune response to a MUC-1 tumor antigen comprising administering an isolated nucleic acid molecule, in addition to producing a method of treating a subject and a method of screening a molecule to generate an immune response to a MUC-1 to a tumor antigen.

Therefore, claims 1-78 lack an inventive step under PCT Article 33(3) as being obvious over Chambon et al and in view of Hoogenboom et al.